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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/528,210
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	First Named Inventor	Stephen R. Smith et al.
	Art Unit	1657
	Examiner Name	Tiffany Maureen Gough
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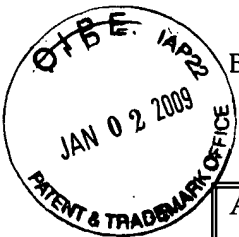
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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCE**

Appellant:	<b>Stephen R. Smith et. al</b>	Examiner:	<b>Tiffany Maureen Gough</b>
Serial No.:	<b>10/528,210</b>	Group Art Unit/TC:	<b>1657</b>
Filing Date:	<b>March 17, 2005</b>	Docket No.:	<b>3323</b>
Title	<b>Antimicrobial Composition and Method for Use</b>		

Date of Deposit: 12-28-08

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**Appellants' Reply**

This is in reply to the Examiner's Answer of October 28, 2008. Specifically, this responds to points raised by the Examiner with respect to the "Grounds of Rejection."

**Status of Claims**

Claims 49-69 are rejected. Claims 49-69 are appealed.

**Grounds of Rejection to be Reviewed on Appeal**

The Appellant requests review of the obviousness rejections of all pending claims. All pending claims, claims 49-69, are rejected under 35 U.S.C. §103(a) as being unpatentable over Unilever PLC (EP 0466244 A1, 1992, hereafter "Unilever") in view of Medipharm (EP 0955061 A1, 1999, hereafter "Medipharm"), Ibrahim (Natural food antimicrobial system, 2000, hereafter "Ibrahim"), and Nippon JP (62145025, 1987, hereafter "Nippon").

### **Argument**

This submission is organized roughly according to the order in which the issues appeared in the Examiner's Answer.

#### **1. The Examiner uses hindsight in an inappropriate manner**

The Examiner applies piecemeal hindsight to construct the art rejections. For example, the Examiner's rejection of claim 49 is made by taking two of the three recited elements from Unilever and the third element from Medipharm and Nippon. The Federal Circuit has provided guidance for when the application of hindsight is inappropriate: "The application of hindsight is inappropriate where the prior art does not suggest that this [chemical component A] could reasonably be expected to manifest the properties and advantages that were found for this particular [chemical composition]. Sanofi-Synthelabo v. Apotex, Inc., --- F.3d ---, 2008 WL 5191848 (Fed. Cir. 2008), citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 36 (1966) (cautioning against hindsight whereby the teachings of the invention are read into the prior art) and KSR v. Teleflex, 127 S.Ct. 1727, 1742 (recognizing "hindsight bias" and "ex post reasoning" as inappropriate in determination of obviousness).

The Appellants' use of a cell wall lysing substance in an *in vivo* treatment could not be reasonably expected to inhibit growth of enteric pathogens; further, the synergistic effects of the cell wall lysing substance combined with egg powder or albumen was not expected and resulted from creative, inventive efforts.

## 2. Unilever is not analogous art

On page 8 of the Examiner's Answer, she describes the antimicrobial properties of the Unilever composition, bolding text focused on the use of the Unilever composition as an "animal feedstuff" and as a "feed additive" as though this is significant to the question at hand of *in vivo* antimicrobial properties. The Appellants submit, however, that it is essentially irrelevant that Unilever is used in conjunction with foodstuffs that may ultimately be consumed (and therefore reside *in vivo*). Unilever's composition as used in foodstuffs is designed to prevent microbial growth before the foodstuff is consumed, i.e. at all times up until consumption; Unilever makes no claims, and is not concerned with, whether its composition has any antimicrobial properties after it is consumed. By the time the Unilever foodstuff is consumed, its composition has done its job of keeping the foodstuff from rotting or becoming infused with bacteria.

In contrast, the working life of Appellants' composition begins upon ingestion, as it works to prevent growth of bacteria in an animal's digestive system.

The Examiner concludes that "the references are analogous because both references are in the art of animal feed modification." However, the analogousness of the references to each other is not the salient question and is not responsive to the Appellants' argument; the question is whether Unilever is analogous to Appellants' invention. Because Unilever is concerned with feedstuffs, and Appellants' invention is concerned with *in vivo* enteric pathogens, Unilever is not analogous art.

3. **There is no teaching in the prior art of a cell wall lysing substance being employed in an *in vivo* composition**

The Examiner asserts that “[t]he art clearly teaches a cell wall lysing substance such as lysozyme (see Unilever, abstract, line 1)” and that “the art of record clearly teaches the claimed composition’s components, which are effective in treating and preventing gastrointestinal infections caused by enteric pathogens”. However, the prior art does not show, and the Examiner has not cited, any use of cell wall lysing substance or its salt in an orally-administerable composition for *in vivo* application.

Further, the Examiner asserts (page 9) that the “claimed components, EDTA, citric acid, nisin, lysozyme and albumen, of appellant’s compositions are well known for their bacteriostatic/bactericidal effectiveness against both gram-positive and gram-negative bacteria” and that “[s]uch pathogens are also well known in the art to be enteric pathogens of the gut.” The Examiner, however, offers no citations of these purportedly “well known” propositions. In particular, it is noted that effectiveness on some gram positive or gram negative bacteria does not indicate effectiveness on all enteric pathogens or the particular pathogens inhibited by Appellants’ claimed invention.

In re Smith, cited by the Examiner, does not justify a conclusion of obviousness. In re Smith describes a simple mechanical device, a paper pocket for the inside of a book. Smith’s claimed pocket was modified from the primary reference (Wyant) in two ways, both shown in other book-related art (Dick and Ruebens). There were no unexpected or synergistic results of employing the techniques of Dick and Ruebens to the Wyant pocket.

Still further, the Appellants note that while KSR holds that teaching, suggestion and motivation is not a replacement for the *Graham v. John Deere* inquiry into obviousness, these factors are still relevant to the inquiry. Therefore, the Appellants assert that it is highly relevant and important to the question of obviousness that there is no teaching, suggestion, or motivation to change Unilever's composition from a feedstuff additive designed to keep food from rotting on the shelf to an orally-administerable composition for inhibiting growth of enteric pathogens by altering it with the addition of egg powder or albumen.

**4. Intended use is not inherent in the prior art**

The Examiner, on page 10 of her Answer, asserts that such "undisclosed use is inherent in the reference composition." The Appellants submit, however, that Unilever provides a composition that does not include all of the elements recited in Appellants' claims; Unilever only provides a composition useful for *ex vivo* applications and would not be effective for the *in vivo* purpose of the Appellants' invention. Therefore the use of Unilever *in vivo* cannot be considered an inherent use.

Further, the Examiner cites no support or evidence for the conclusory statement that "such undisclosed use is inherent in the reference composition." "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd.Pat. App. & Interf. 1990). The Examiner has provided no such basis in fact or technical reasoning.



5. **It is not obvious to combine *in vivo* and *ex vivo* agents in a composition to operate *in vivo***

In its response of August 15, 2007, the Appellants included the following sentence that seems to be a source of a misunderstanding (page 10 of the Examiner's Answer):

While these references may provide some justification or expectation of success for adding egg or albumen to a composition where the antimicrobial activity of the composition occurs *in vivo* (i.e. in the gut of livestock) and targets the growth of enteric pathogens, the teachings of these references cannot be distorted to provide motivation for the addition of egg or albumen to an antimicrobial composition which targets the suppression of bacterial growth *ex vivo* (i.e. on inanimate objects).

The argument that the Appellants were making, entirely consistent with their assertion of nonobviousness, is that IF Unilever WERE a composition that worked *in vivo*, then it might be reasonable to add another substance known to have an *in vivo* effect. But, since Unilever, is a composition designed to work *ex vivo*, there would be no reason or motivation to add an *in vivo*-effective substance to it, nor any reason to believe it would be effective *in vivo*. The Appellants were simply making their oft-stated assertion in this case, that *in vivo* and *ex vivo* environments are different (in temperature, humidity, pH, time constraints involved in digestion and bioabsorption), and there is no reason to expect *in vivo* success of a combination of *ex vivo* and *in vivo* agents. In other words, it would not be obvious to arrive at the Appellants' claimed composition.

6. **Appellants' preambles give meaning to the claims**

A preamble can indeed be part of a claim where the preamble adds "life, meaning, and vitality" to a claim. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182

F.3d 1298, 1305 (Fed. Cir. 1999). Claim preambles have been deemed part of a body of a claim in many decided cases.<sup>1</sup> The Federal Circuit has explained that the "entirety of the patent" must be reviewed to understand the effect that preamble language has on the scope of a claim at issue:

No litmus test can be given with respect to when the introductory words of a claim, the **preamble**, constitute a statement of purpose for a device or are, in themselves, additional structural limitations of a claim. To say that a **preamble** is a limitation if it gives "meaning to the claim" may merely state the problem rather than lead one to the answer. The effect **preamble** language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.

Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257, 9

U.S.P.Q.2d (BNA) 1962, 1966 (Fed. Cir. 1989).

Further, where it is apparent from the specification that the inventor was working on a particular problem (e.g., displaying binary data on only raster scanned display devices rather than on all types of display systems), the scope of the claims has been limited to the problem so discussed in the descriptive portion of the specification and recited in the claim **preamble**, though not repeated in the body of the claim ("raster scanned display"). General Elec. Co. v. Nintendo Co., Ltd., 179 F.3d 1350, 50 U.S.P.Q.2d (BNA) 1910, 1918–19 (Fed. Cir. 1999).

Throughout Appellants' descriptive portion of the specification, Appellants describe that the problem discussed is that of digestive problems resulting from microbes that grow in the gut of an animal. Finding a composition that is effective in combating microbes in the environment of the gut

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<sup>1</sup> Examples of these include: General Electric Co. v. Nintendo Co., 179 F.3d 1350 (Fed. Cir. 1999), Electro Scientific Industries, Inc. v. Dynamic Details, Inc., 307 F.3d 1343 (Fed. Cir. 2002).

is the problem addressed by the Appellants inventive efforts and the claimed composition. Accordingly, the Appellants' preamble in all independent claims, referencing that the composition is "orally administered" and that its purpose is "for suppressing the growth of enteric pathogens in the gut of livestock" are intended to be limiting, and should properly be considered limiting.

Further, the purpose of the composition, as expressed in the preamble and throughout the description, is relevant to consideration of whether the recited combination would be obvious in light of the prior art. Because the Appellants were solving the problem of suppressing the growth of enteric pathogens within the gut of livestock, it was not obvious to draw on teachings from references that addressed *ex vivo* microbe suppression.

7. **The Appellants employed creativity in trying a long list of possible components before arriving at the claimed composition**

In our Appeal Brief, the Appellants presented a list of ingredients that the Appellants tried using before trying the resulting claimed product. This list is long. The named inventors are at least of ordinary skill in the art, and, were the claimed combination obvious to them, they surely would not have bothered to try the long list presented prior to trying the claimed composition.

Further, the Examiner notes, and we concur, that the list is "quite creative and inventive". It was this creative and inventive approach that led to the claimed composition.

8. **FIG. 2 shows synergistic effect of claimed composition**

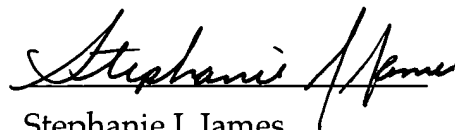
The Examiner dismisses the Appellants' claim as to the showing presented in FIG. 2. The meaning of FIG. 2 is described in the specification, at Paragraphs 0047-0050. Specifically, "Figure 2 illustrates the MIC plates of *Clostridium perfringens* inoculated with a 100 times dilution of an overnight culture. In this pilot study, the mixture (Blend 1) contains lysozyme, albumen and citric acid in a ration of 1:3:1. Figure 2 illustrates that there is an efficacy for inhibiting *Clostridium perfringens* at approximately 50ppm when using the above-described Blend 1 on MIC plates." Therefore, the meaning of FIG. 2 can be understood in conjunction with the associated text in the specification.

#### CONCLUSION

The Appellants respectfully requests a decision by the Board that the claims are not obvious in light of the cited art.

Respectfully submitted,  
Neova Technologies, Inc.  
By its attorneys:

Date: 12/29/08



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